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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,475	07/16/2003	Judith A. Friese	7098.US.O1	8616

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,475	FRIESE ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *37-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 1-17, 19-36 in the reply filed on 1/23/06 is acknowledged. The traversal is on the ground(s) that it would not be a burden to search both Groups. This is not found persuasive because the calibrator composition and method are distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

The abstract of the disclosure is objected to because it is not directed to the presently claimed invention. Correction is required. See MPEP § 608.01(b).

No priority is claimed for the present application filed 7/16/03. Please inform the examiner of all related applications, patented, pending or abandoned.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 19-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 10/721,031. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present independent claims include a functional limitation regarding stability.

Claims 1-17, 19-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 11/248,650. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present independent claims include a functional limitation regarding stability.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17, 19-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bergmann in view of each of Chen and Flaa.

Bergmann (5,541,116) entitled "Method for the Stabilization of Endogenous, Physiologically Active Peptides" teaches in column 2 line 21, EDTA, and on lines 38-39, ANP. In column 3 lines 20-24, EDTA is a protease inhibitor and a buffer is added. In column 4 line 26 a phosphate buffer is employed. In column 5 line 2 aprotinin is shown.

The claims differ from Bergmann in that they specify a pH range and some of the dependent claims include additional stabilizing substances.

Chen (6,525,102 B1) entitled "Stabilized Liquid Polypeptide Containing Pharmaceutical Compositions" teaches in column 1 line 28, pH affects stability of polypeptides. In column 2 lines 24-29, buffers are described. In column 2 line 40 EDTA is shown to increase stability of polypeptides. In column 10 first paragraph, pH ranges of 5-6.5 are taught regarding the pH optimum for stability of a particular polypeptide of interest. In column 24 lines 25-37, how the optimum pH was determined is shown.

Flaa (WO 96/27661) entitled "Stabilizing Solutions for Proteins and Peptides" teaches on page 7 last paragraph, a composition for stabilizing proteins containing buffer, albumin, chelating agent, reducing agent at a mildly alkaline pH. On page 8 the stabilizing protein may be albumin or casein. On page 9 protease inhibitors and preservatives may be used. On page 9 line 9 phosphate buffers are shown. On page 10 line 5 BSA is taught. On page 10 line 25 EDTA is seen. On page 11 line 10, the pH range is 5-7.5. On page 11 line 15 aprotinin is shown along with other known protease inhibitors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to stabilize natriuretic peptides as taught by Bergmann at the pH ranges and with the additional substances taught by each of Chen and Flaa because both Chen and Flaa teach stabilizing various polypeptides for the same function as claimed at the pH range and with the substances as presently claimed. To stabilize any polypeptide with a pH range and substances known to stabilize polypeptides with the expected results would have been obvious. No novelty is seen in the claimed compounds such as sodium hydroxide in obtaining a desired pH range or to make a buffer solution.

Claims 10, 11, 27, 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain specific reagents, does not reasonably provide enablement for "a stabilizing compound," "a biocide", "a protein", "a polymer". The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 10, 11, 27, 28 the terms above lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such substance would work in the instant invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.

2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.

3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.

4. The nature of the invention is complex and unpredictable.

5. State of the prior art indicates that most related substances are not effective for the claimed functions.

6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of compounds.

8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 19-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 line 2, "the level" lacks antecedent basis. In claim 1 last line, "12 months or more" does not state how many more and reads on infinity. Claim 1 is a composition claim and it is defined only in functional terms regarding pH and stability, not what it contains. No components are defined so claim 1 reads on a dilute solution of vinegar.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
Todteben (US 2005/0136542 A1) teaches stabilizing BNP and other proteins by adjusting pH in paragraph 37.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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